Department of The Army
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Boards, Commissions, and Committees
HUMAN SUBJECTS RESEARCH REVIEW BOARD

This is a minor revision; however, changes and additions have been made throughout.

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1. ESTABLISHMENT. The Human Subjects Research Review Board (HSRRB) is hereby established as a continuing committee.

2. PURPOSE. This regulation describes the manner in which The Surgeon General (TSG) exercises approval authority for research and clinical investigation protocols submitted under the provisions of ARs 40-7, 40-38, 70-25, and TB MED 525, that involve the use of human subjects. It establishes the HSRRB, herein called the "Board." The HSRRB formerly functioned as the Army Investigational Drug Review Board (AIDRB), which reviewed the applications in accordance with AR 40-7. The AIDRB review functions included detailed scientific review, but this function is now the primary responsibility of the first commander in the review chain. This regulation is compatible with the Food and Drug Administration's (FDA's) regulation in part 50, title 21, Code of Federal Regulations (21 CFR 50) and the Department of Health and Human Services (HHS) regulation in 45 CFR 46.

3. REFERENCES.

a. 5 USC app 2 (Federal Advisory Committee Act).

b. 10 USC 980 (Limitation on the Use of Humans as Experimental Subjects).

c. 21 CFR 50 (Food and Drug Administration).

d. 45 CFR 46 (Department of Health and Human Services).

e. Memorandum of Understanding between the Food and Drug Administration and the Department of Defense, 21 May 1987.

f. DOD Directive 3216.2 (Protection of Human Subjects in DID-Supported Research).

g. DOD Directive 6000.8 (Funding and Administration of Clinical Investigational Programs).

h. DOD Directive 6465.2 (Organ Disposal After Drug Autopsy).

i. AR 40-7 (Use of Investigational Drugs in Humans and the Use of Schedule I Controlled Drug Substances).

j. AR 40-38 (Clinical Investigation Program).

k. AR 70-25 (Use of Volunteers as Subjects of Research).

l. AR 70-64 (Management of Controlled Substances, Ethyl Alcohol, and Hazardous Biological Substances in Army Research, Development, Test, and Evaluation Facilities).

m. AR 600-50 (Standards of Conduct for Department of the Army Personnel).

n. AR 600-110 (Identification, Surveillance, and Administration of Personnel Infected with Human Immunodefiencey Virus (HIV)).

o. TB MED 525 (Occupational and Environmental Health Control of Hazards to Health form Ioning Radiation Used by the Army Medical Department).

4. RESPONSIBILITIES.

a. The HSRRB is functionally similar to a civilian Institutional Review Board (IRB) as described in 45 CFR 46, but has somewhat different powers of authority compared to an IRB. Within Department of the Army (DA), authority to approve the use of human subjects in research and clinical investigation, as specified in b below, is vested in TSG, acting on the recommendations of the HSRRB. Outside DA, IRBs tend to be vested with this authority.

b. The HSRRB is the principle body of the Office of The Surgeon General (OTSG) for the assessment of practices and procedures by which DA employs human subjects in research, development, test, and evaluation activities including clinical investigation activities. The Board will consider and recommend policy to TSG to maintain the quality of practices consistent with moral, ethical, and legal standards. It will consider protocols submitted to TSG for approval and will make written recommendations for approval, disapproval, or deferral to TSG. TSG is the final approving authority for all research using human volunteers except—

(1) Research related to nuclear, biological, or chemical threat agents. TSG will forward the protocol, together with the Board's recommendation, through the Secretary of the Army to the Under Secretary of Defense for Acquisition who is the approving authority for such research.

(2) Research related to alcohol and drug abuse programs. The Surgeon General will forward the protocol, together with the Board's recommendations, to the Deputy Chief of Staff for Personnel who is the approving authority for such research.

(3) Research activities for which approval authority has been delegated to the Commander, U.S. Army Health Services Command (HSC).

c. Except for medical or military emergencies, responsibilities for the Board's review process include, but are not limited to—

(1) Clinical investigation protocols involving the basic disease process or new treatment procedure, drug or device conducted under the provisions of AR 40-38 or AR 40-7, except where approval authority has been delegated along military command lines.

(2) Protocols involving the use of human subjects as the direct object of research under the provisions of AR 70-25, except where limited approval authority for minimal risk, type, and like protocols has been delegated to the Chairman, HSRRB.

(3) Protocols detailing operational tests of military weapon systems, vehicles, aircraft, and other material for major commands upon referral by that commander.

d. For protocols which the HSRRB reviews, the Board will determine which projects require review more often than annually.

e. When a protocol is approved or disapproved by TSG, the principal investigator's major commander will be notified in writing, on behalf of TSG, by the Chief, Human Use Review and Regulatory Affairs Office (HURRAO). The written notification will normally contain the following information and responsibilities:

(1) TSG's decision with accompanying recommendations. If revisions to the protocol are to be made, such revisions should be submitted to HURRAO (SGRD-HR) within 30 days.

(2) The responsibilities of the principal investigator to TSG through HURRAO, are—

(a) To promptly report changes or unanticipated problems in a research activity. Normally, changes may not be initiated without TSG approval, except where necessary to eliminate apparent immediate hazards to the human subject or others.

(b) To immediately report by telephone (AUTOVON 343-2165 or (301) 663-2165) (non-duty hours, call AUTOVON 343-7114 or (301) 663-7114 and ask for the USAMRDC duty officer), serious or unexpected adverse experiences which occur to the human subjects or others. For those projects involving an investigational New Drug (IND) application sponsored by TSG, FDA Form 1639 (Adverse Reaction Report (Drugs and Biologics)) should be used and a written report will follow the initial telephone call within 3 working days. Copies of FDA Form 1639 can be obtained from HURRAO.

(c) To promptly report any change of investigators.

(d) To prepare, at a minimum, an annual progress report or final report in accordance with 21 CFR 312.33.

(e) To immediately report to HURRAO knowledge of a pending compliance inspection by the FDA or other outside governmental agency concerning clinical investigation or research.

(f) IND applications, annual reports, and other information required by FDA on DA IND's may be released to the FDA on behalf of TSG by the Board Chairmen or his or her designee.

(g) The Chairmen or his or her designee may act for TSG in administrative matters relating to the HSRRB and has authority to suspend or terminate approved research or clinical investigation projects.

(h) Normally, the HSRRB will meet monthly, with agenda and meeting arrangements formulated by HURRAO.

5. BOARD MEMBERSHIP.

a. General comments.

(1) The HSRRB will have a minimum of 13 voting members, with varying backgrounds to promote complete and adequate reviews of research activities commonly conducted by DA. The Board must be sufficiently qualified, through the experience and expertise of its members, and the diversity of the members' backgrounds, including consideration of the racial and cultural attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the HSRRB must be able to ascertain the acceptability of proposed research in terms of DA commitments and regulations, applicable law, and standards of professional conduct and practice. The HSRRB will, therefore include persons knowledgeable in those areas. If the HSRRB regularly reviews research that involves a vulnerable category of subjects, it should include one or more individuals who are primarily concerned with the welfare of these subjects.

(2) The HSRRB will not consist entirely of members of one profession. However, it must be composed of military personnel and civilian employees of the Federal Government.

(3) The HSRRB must include at least one member whose primary concerns are in a nonscientific area and one member who is not affiliated with the DA.

(4) The HSRRB will not have a voting member participate in initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Board. A discussion of conflict of interest is in appendix A.

(5) The HSRRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the Board.

b. Voting members. The Board will consist of the following voting members appointed by TSG—

(1) The Assistant Surgeon General for Research and Development or his or her designee (Chairman).

(2) Chief, HURRAO, USAMRDC.

(3) The Command Judge Advocate, USAMRDC.

(4) Three members who are physicians and qualified to evaluate research proposals. At least one of these members should be a Board certified specialist in surgery and another in internal medicine.

(5) One member professionally qualified in pharmaceutical sciences.

(6) One member professionally qualified in behavioral or allied medical sciences.

(7) One member who is professionally qualified in nursing sciences

(8) A chaplain or other member of the clergy.

(9) One member who is not affiliated with the DA.

(10) An enlisted member whose primary concerns are in a nonscientific area.

(11) One civilian member qualified to evaluate the acceptability of research proposals in terms of community attitudes.

c. Non-voting member. Investigational Drug Review Officer, HURRAO (Recorder).

d. Alternates. Each voting member will recommend at least one alternate member. Such recommendations will be evaluated by the Board and submitted to TSG for approval. Alternates will be encouraged to attend Board meetings along with the voting member in order to gain familiarity with policies and procedures.

e. Ad hoc subcommittees. The Chairman may appoint subcommittees of the Board to consider special issues or special types of research protocols. At least one member of each subcommittee will be a voting Board member.

f. Quorum. A Board recommendation will be based on a convened quorum consisting of eight voting members or alternate members, of which two must be physicians, and one whose primary concerns are in nonscientific areas. In addition, an opinion from the USAMRDC Command Judge Advocate or his or her representative will be required before a formal Board decision can be made. This opinion may be submitted to the Board in writing if the legal representative is unable to attend.

g. Administrative support. The HURRAO will supply administrative support for HSRRB activities.

6. Criteria for HSRRB recommended approval of protocols and other actions.

a. In order to recommend research for approval, the HSRRB will determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized—

(a) By using procedures which are consistent with sound research design and that do not unnecessarily expose subjects to risk.

(b) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(c) By compliance with current Army regulations and policies.

(2) The protocol has been reviewed and approved on the basis of scientific merit.

(3) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the HSRRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The HSRRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(4) Selection of subjects is impartial. In making this assessment the HSRRB should take into account the purposes of the research and the setting in which the research will be conducted.

(5) The HSRRB will require documentation of informed consent in accordance with appendix B. The HSRRB will require that the informed consent is obtained from the research subject in advance. If the research subject is unable to provide informed consent, then the HSRRB will require that the research is intended to be beneficial to the subject and that informed consent is obtained from a legal representative of the subject in advance.

(6) Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(8) Where appropriate, the research plan makes provisions for obtaining informed consent from the patient or the legally constituted nest of kin when tissues or body fluids to be used in the research are obtained by autopsy or from elective surgery.

(9) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such persons with acute or severe physical or mental illness, persons who are economically or educationally disadvantaged, or persons who are prisoners, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(10) Where any subjects who do not comprehend English will be enrolled in a study, the protocol submitted to the HSRRB includes an accurate, non-English translation of the consent form.

b. Actions on recommendations by the Board will be based on a simple majority vote of members present.

7. HSRRB RECORDS.

a. The HURRAO will maintain documentation of the HSRRB activities, including—

(1) Copies of all research protocols reviewed, scientific reviews, and other documentation that normally accompany the proposals, approved sample consent documents, progress reports submitted by the investigators, and reports of injuries to subjects.

(2) Minutes of HSRRB meetings which show attendance at the meetings; actions taken by the HSRRB; the vote on these actions, including the number of members voting for, against, and abstaining and the basis for requiring changes in or disapproving research.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the HSRRB and the investigators.

(5) A list of HSRRB voting members and alternates.

(6) Statements of significant new findings provided to subjects.

(7) Copies of all TSG-sponsored IND and Investigational Device Exemption (IDE) submissions, amendments, and correspondence.

(8) Other written procedures for the HSRRB which are not covered by this regulation.

b. The records required by this regulation will be retained for at least 3 years after completion of the research, and the FDA regulated records will be accessible for inspection by authorized representatives of the FDA at reasonable times and in a reasonable manner.

8. MINIMAL RISK PROTOCOLS.

a. Minimal risks protocols are those in which the proposed risks are not considered greater than those encountered in the subject's daily life or during routine physical or psychological examinations. Appendix C contains examples of minimal risk studies. Research involving investigational drugs is always considered more than minimal risk.

b. Research involving adult human subjects at minimal risk that neither involves investigational drugs or third party consent, nor otherwise requires formal TSG approval, may be approved by the Chairman of the HSRRB or his or her designee.

9. TYPE PROTOCOLS.

a. A master "type protocol" is an in-house study plan involving the use of human subjects in a group of closely related and similar studies that differ from each other in ways which are unlikely to change the degree of risk involved. A master "type protocol" does not contain a detailed plan of every possible study that might be undertaken, but includes a description of conditions under which the studies will be conducted, and the standards that will be followed to safeguard the subject. The equipment to be used, including safety equipment, must be discussed in detail, along with all conditions to which the subject will be exposed, and the deviations from normal vital signs that will be allowed prior to suspension of the subject's participation. The use of a master "type protocol" is acceptable only if the conditions under which the study is being conducted are so well understood that the described safety limits are clearly acceptable for the subjects proposed to be included. All master "type protocols" will be approved by TSG's HSRRB. Approval of a master "type protocol" does not permit evaluation of all the factors required prior to approval of a particular study, each individual study to be conducted under an approved "type protocol" must be evaluated individually by a documented scientific review process and supported by a human use committee.

b. Research involving human subjects under a previously approved master "type protocol" may be approved by the Chairman of the HSRRB or his or her designee.

10. LIKE PROTOCOLS.

a. A "like protocol" is a protocol normally submitted by a new principal investigator that is essentially identical to a protocol previously approved by the HSRRB.
b. Research involving human subjects under a "like protocol" may be approved by the Chairman of the HSRRB or his or her designee.

11. REPORTING ADMINISTRATIVE APPROVAL OF PROTOCOLS. All protocols administratively approved (without formal HSRRB action) will be reported by HURRAO in the minutes of the next HSRRB meeting. Examples of types of research which may be expeditiously reviewed and administratively approved can be found in appendix C. Research submitted under "type protocols" or as a "like protocol" (see paras 9 and 10) may also be administratively approved.

12. INFORMATION FOR NEW BOARD MEMBERS. In addition to references listed in paragraph 2, new Board members will find the attached appendixes to be of value. Appendixes B and C are extracts of current Health and Human Services (HHS) regulations.

13. ADMINISTRATIVE SUPPORT.

a. The Human Use Review and Regulatory Affairs Office will supply clerical support.

b. Office space (meeting facilities) will be provided by OTSG.

c. TDY funding will be considered for exceptional travel circumstances on a case-by-case basis.

APPENDIX A
CONFLICT OF INTEREST

A-1. It is essential that the members of the HSRRB continue to be perceived and, in fact, are free from conflict of interest in their daily duties and especially in regards to the protocols they review.

A-2. The issue of conflict of interest has been addressed by Public Law, DOD Directive, and Army regulation. The situations discussed below are merely examples of the types of activities and relationships that may result in conflicts or the appearance of conflicts of interest. They are by no means the only way that conflicts arise.

a. The potential for personal or financial gain. A Board member who is deliberating a protocol that is to be performed by a contractor, in which the member or a member of his or her immediate family is a corporate officer, stockholder, consultant or employee, could be accused of conflict of interest if he or she voted on the protocol, regardless of his or her vote.

b. The potential for personal reward. A Board member who is affiliated with a protocol in the capacity of principle, associate, or co-investigator, could be accused of conflict of interest if he or she voted on the protocol, regardless of his or her vote.

c. Command influence. The perception that command influence is the norm in the military pervades in the community. However, the mission (for example the purpose

of the research) should not override or obscure its methods. It is imperative that the Board, through its members, continue to be recognized as a reasonable, deliberative body, whose bias is the safety and welfare of the research subject. It is incumbent upon each Board member to assure his or her concerns regarding the moral, ethical, and legal issues of each protocol are answered to his of her satisfaction before voting according to his or her conscience.

APPENDIX B
ELEMENTS OF INFORMED CONSENT

B-1. BASIC ELEMENTS OF INFORMED CONSENT. In seeking informed consent, the following information will be provided to each subject. Investigators should use a DA Form 5303-R (AR 70-25).

a. Title of the study and location (specify address) where it is to be conducted.

b. Name of principal investigator, and associate(s), if applicable, conducting the study.

c. A statement that the study involves research and an explanation of the purpose of the research. In general, the informed consent should—

(1) Be readable (short, clear, simple, declarative sentences).

(2) When feasible, use non-medical language that is easily understood by the subject. The age group, reading level, and education of prospective subjects must be taken into consideration.

(3) Include a translation of the consent form into the native language of the non-English speaking subjects who are to be enrolled in the study. The HURRAO may make arrangements to have the non-English translation verified by an individual fluent in both languages.

(4) Speak to the research subject in the first person singular, “I” and/or “you.”

(5) Always be explicit in detailing inclusion and exclusion criteria.

(6) Be provided to the subject and legal representative. There should be a statement in the document to the effect that the subject and legal representative will be provided a copy.

d. A statement indicating the expected duration of the subject’s participation (the number of hours, days, etc.).

e. A description of the procedures to be followed and identification of any procedures which are experimental.

(1) Briefly explain the study design relative to what will be done to the subject (in blind or double-blind studies, subjects must be informed that they may receive either the experimental or a placebo). If a placebo is used, its contents should be described.

(2) Specify what is required of the subject (hospital visits, blood donation, etc.). If blood is to be drawn, the amount(s) to be drawn should be expressed in lay terms.

(3) Procedures, pharmaceuticals, and devices that are experimental should be identified. (If an IND or IDE has been secured from the FDA, the subject should be advised that the IND or IDE is permission for the study to be undertaken and does not indicate FDA approval for the routine use of the drug or device in the method proposed in the protocol. If a drug or device covered under an IND or IDE is involved, it must be clearly indicated in the consent form that it is investigational for the purposes of this research.)

(4) Although a subject may be familiar with the procedures, never assume that he or she comprehends everything.

f. A description of any reasonably foreseeable risks or discomforts to the subject.

(1) For studies of potential subject benefit, describe risks unique to the study; estimate their severity and likelihood; and/or compare these risks with risks which the subject might encounter in the course of his or her daily activities. If similar research has been conducted in the past, describe the incidence of adverse effects or injuries occurring in the past.

(2) For studies of no potential benefit to the subject, list all risks which are more than "minimal" (not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine medical tests).

g. A description of any benefits to the subject or to others which may reasonably be expected form the research (mention renumeration, if any). If subjects are to be paid for participation in a research study, those payments should not be unduly large. Lump sum payments where all or most of the payment for study participation is withheld until completion of the study should be avoided since this situation may present questions of coercion of subjects to volunteer for, or continue with, a research study.

h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (for example, whether treatment is available outside the protocol).

i. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. It should be noted that representative of the USAMRDC (and, where applicable, the FDA and/or HSC may inspect the records of the research. For studies utilizing military personnel as subjects, the following

wording may be substituted: "All data and medical information obtained about you as an individual will be considered privileged and held in confidence; you will no be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical command authorities, and applicable regulation notes the possibility that representatives of the USAMRDC (and the FDA) may inspect the records of the research."

j. For USAMRDC sponsored research, the following statement must be incorporated into the consent form: "You are authorized all necessary medical care for injury or illness which is the proximate result of your participation in this research. Contractors must provide such medical care when conducting research on civilian subjects." (Where private citizens are to be enrolled, the following statement should be included: "Other than medical care that may be provided and any other renumeration specifically stated in this informed consent, there is no other compensation available for my/your participation in this research study; however, I understand this is not a waiver or release of my/your legal rights.")

k. An explanation of whom to contact for answers to pertinent questions about the research—

(1) Study and in the event of a research-related injury to the subject.

(2) Subjects' rights.

The investigator(s) should be contacted for (1); the HUC, IRB, or legal office for (2). This information should include addresses and telephone numbers.

l. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

m. Provide space for the date, signature, typed, or printed name, and permanent address of the subject and legal representative; and signature and typed or printed name of the witness.

(If an advertisement is to be used to recruit volunteers for a study, the content of that advertisement must be approved by the HUC to ensure that the information is not misleading. The advertisement should be limited to the name and address of the clinical investigator, purpose of the research, summary of eligibility criteria, a straightforward and truthful description of benefits, and location of the research, and the person to contact for further information.)

B-2. Additional elements of informed consent. When appropriate, one or more of the following elements of information will also be provided to each subject:

a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is, or may become, pregnant) that are currently unforeseeable.

b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the research.

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue to participate will be provided to the subject.

f. The approximate number of subjects involved on the study.

g. Precautions to be observed by the subject before and following the study.

B-3. The informed consent requirements in this regulation are not intended to preempt any applicable Federal, State, or local laws that require additional information to be disclosed for informed consent to be legally effective.

B-4. Nothing in this regulation is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local laws.

APPENDIX C
EXAMPLES OF RESEARCH ACTIVITIES WHICH ARE MINIMAL RISK AND MAY RECEIVE EXPEDITED REVIEW

C-1. Collection of hair and nail clippings in a non-disfiguring manner; of deciduous teeth; and of permanent teeth if patient care indicates a need for extraction.

C-2. Collection of excreta and external secretions including sweat and uncanulated saliva, of placenta at delivery, and of amniotic fluid at the time of rupture of the membrane before or during labor.

C-3. Recording of data from subjects who are 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This category includes the use of physical sensors that are applied either to the surface of the body or at a distance and do

not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. This category does not include exposure to electromagnetic radiation outside the visible range (for example, x rays or microwaves).

C-4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an 8-week period and not more often than two times per week, from subjects who are 18 years of age or older, and who are in good health and not pregnant.

C-5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques.

C-6. Voice recordings made for research purposes such as investigations of speech defects.

C-7. Moderate exercise by healthy volunteers.

C-8. The study of existing data, documents, records, pathological specimens, provided that confidentiality of subjects is protected.

C-9. Research on perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve appreciable stress to subjects.

SGRD-HR (27 Dec. 88)

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